UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,477	06/22/2001	Arnold J. Reuser	24512-X	6846

20529 7590 05/01/2003

NATH & ASSOCIATES
1030 15th STREET
6TH FLOOR
WASHINGTON, DC 20005

EXAMINER	
PRATS, FRANCISCO CHANDLER	

ART UNIT	PAPER NUMBER
1651	15

DATE MAILED: 05/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/886,477	REUSER ET AL.	
	Examiner	Art Unit	
	Francisco C Prats	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *1-25 and 27-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5, 12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-37 are pending.

Election/Restrictions

Applicant's election with traverse of the group III invention, claim 26, in Paper No. 14, filed April 17, 2003, is acknowledged. The traversal is on the ground(s) that no serious burden exists in examining all claims presented because the inventions in groups I through IV show identical overlap with each other, and because a filing fee for examination of all claims has been paid.

This is not found persuasive because, contrary to applicant's assertion of identical overlap, groups I, II, IV and V are classified differently than elected group III. Note specifically that for purposes of the initial restriction requirement a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02. That *prima facie* showing may be rebutted by appropriate showings or evidence by the applicant. Although applicant states that search and examination of all claims does not place an undue burden on the examiner, applicant has provided no showing or

evidence whatsoever in support of that argument as required by MPEP § 808.02, to rebut the serious burden presumed when inventions are classified differently.

Moreover, with respect to restriction between elected group III and group II, note specifically that group II recites products, and elected group III is directed to a method of therapeutic use of the product. Moreover, group II recites purity limitations not present in group III. Thus, to the extent that class 424, subclass 94.61, must be searched for both groups, the patentability of the two inventions clearly involves consideration of substantially different issues. Moreover, in view of the fact that group II requires searching class 435, subclass 201, in addition to class 424, subclass 94.61, it is clear that search and examination of both elected group III and group II constitutes significant burden.

Lastly, the fact that applicant has paid a filing fee does not render the restriction improper. Using applicant's logic, payment of a filing fee would entitle examination of any set of claims, regardless of the degree of difference between the inventions presented.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-25 and 27-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 14, filed April 17, 2003.

Claim 26 is examined on the merits.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 and 119(e) as follows:

Applicant claims ultimate priority to Provisional Application Serial No. 60/001,796, filed August 2, 1995. This priority claim cannot be granted because the line of cases stemming from the '796 provisional applicant lacks copendency with the case under examination. Specifically, applicant asserts that this application is a continuation in part of 09/770,253, which is in turn a continuation in part of the '796 provisional application. Continuations in part of provisional applications do not exist. Rather, one can obtain priority to a provisional application only by filing a non-provisional application within 12 months of filing the provisional

application. See 35 U.S.C. 119(e). The '253 application was filed on January 29, 2001, more than 12 months after the August 2, 1995, filing date of the '796 provisional application. Applicant's claim of priority from the '253 application to the '796 provisional application clearly cannot be granted.

It is noted that Application Serial No. 08/700,760 was filed on July 29, 1996, less than 12 months after the August 2, 1995, filing date of the '796 provisional application. However, the '760 application ultimately issued as U.S. Pat. No. 6,118,045, on September 12, 2000. Because the '253 application was not filed until January 29, 2001, the '253 application was not copending with the '760 application. The '253 application therefore cannot be granted priority based on the '760 application.

Applicant also claims priority through the '253 application to Provisional Application Serial No. 60/111,291, filed December 7, 1998, which was a priority document to PCT/US99/29042. This priority claim cannot be granted for two reasons. First, as discussed above, a priority claim to a provisional application must be made within twelve months of the filing of the provisional application. See 35 U.S.C. § 119(e). The '253 application was filed January 29, 2001, more than 12 months after the December 7, 1998, filing of the '291 provisional.

Second, the '253 application contains no inventors in common with either the '291 provisional application or the '042 PCT application. Thus, even if the PCT application is considered to be copending with this application or the '253 application, priority cannot be granted because there are no inventors in common between this case and the '253 application, and the '291 provisional application and the '042 PCT application.

In sum, the earliest priority date applicant can be granted is January 29, 2001, the filing date of Application Serial No. 09/770,253, the C-I-P parent of this case.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting

claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 26 recites the broader recitation of purity of 95%, and the claim also recites preferable purities of 99% and 99.9%, which are the narrower statements of the range/limitation.

Claim 26 is also rendered indefinite by the recitations "preferably" and "more preferably." Because a preference is an entirely subjective criterion, and because it is not clear when the preferences must be exercised, the claim must be considered indefinite.

Also, the recitation "a-glucosidase" is technically an incorrect designation for the enzyme. Specifically, the enzyme

may be correctly referred to as -- α-glucosidase -- or -- alpha-glucosidase --.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (f) he did not himself invent the subject matter sought to be patented.

Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Van Corven et al (WO 99/51724).

Van Corven describes the intravenous administration of up to 10 mg purified human acid α-glucosidase to patients suffering from lysosomal enzyme deficiency disease. See, e.g., page 32, lines 4-19. Note specifically that the reference inherently

meets the claimed limitation requiring liver, heart and muscle cell uptake because the reference describes administering the same ingredient to the same patient at the same dosage. Note further that the reference also discloses the claimed purity limitation, stating on page 21, lines 13-17 that the most preferred pharmaceutical compositions comprise essentially homogeneous enzyme. A holding of anticipation is clearly required.

Claim 26 is rejected under 35 U.S.C. 102(a) as being anticipated by Van Bree et al (WO 00/34451).

Van Bree describes the intravenous administration of up to 40 mg purified human acid α-glucosidase to patients suffering from Pompe's disease, and that the enzyme will be taken up by liver, heart and muscle cells. See, e.g., page 18, line 7, through page 19, line 20. Note further that the reference also discloses the claimed purity limitation, stating on page 5, lines 22-25, that the most preferred pharmaceutical compositions comprise essentially homogeneous enzyme. See also page 17, lines 23-28, disclosing greater than 95% pure enzyme from transgenic rabbits. A holding of anticipation is clearly required.

Claim 26 is rejected under 35 U.S.C. 102(a) and 102(e)(2) and 102(f) as being anticipated by Reuser et al (U.S. Pat. 6,118,045).

Reuser discloses the administration of human acid α-glucosidase to a human patient suffering from Pompe's disease, wherein the enzyme is administered intravenously, and wherein the enzyme is purified to homogeneity. Note specifically that the reference inherently meets the claimed limitation requiring liver, heart and muscle cell uptake because the reference describes administering the same ingredient to the same patient at the same dosage. See claims 18-20, at column 18, lines 38-47. Note further that therapeutic dosages are defined therein as generally from about 0.1 to 10 mg purified enzyme per kilogram of body weight. See column 12 at lines 20-23. A holding of anticipation is clearly required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 26 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-20 of U.S. Patent No. 6,118,045. Although the conflicting claims are not identical, they are not patentably distinct from each other because, although they recite a product, the patented claims use terminology clearly suggesting the treatment of Pompe's disease by intravenous administration of homogeneous enzyme. Moreover, by properly construing the term "therapeutically effective dosage" by reference to the specification (column 12, lines 20-20), it is clear that such dosages fall within those present in the claims under examination. Further still, the determination of suitable dosages was well within the purview of the artisan of ordinary skill at the time of applicant's invention. Claim 26 is clearly not patentably distinct from claims 18-20 of the '045 patent.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Francisco C Prats
Primary Examiner
Art Unit 1651

FCP
April 29, 2003